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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/658,390	09/08/2000	Arthur J. Coury	FTI 126	3456

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EXAMINER

WANG, SHENGJUN

ART UNIT

PAPER NUMBER

1617

DATE MAILED: 09/09/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/658,390

Applicant(s)

COURY ET AL.

Examiner

Shengjun Wang

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 14 June 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 38-53 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 38-53 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

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### DETAILED ACTION

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on June 14, 2004 has been entered.

### *Claim Rejections 35 U.S.C. 103*

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 38-53 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zajaczkowski (US 5,726,250) in view of Hubbell (US 5,410,016, IDS).

Zajaczkowski teaches a crosslinked water-absorbent copolymers useful for wound dressing or medical adhesive. The copolymer is made of macromers and monomers, wherein the macromer has a hydrophilic region, which may be polyethylene glycol, and acrylate terminal group, with molecular weight about 300-50,000, and preferably 300 to 3000; the monomers may be hydrophilic, such as hydroxyethyl acrylate, vinyl pyrrolidone, diacetone acrylamide, or hydrophobic, such as butyl acrylate. The amount of macromer may up to 35 % by weight. The crosslinking may be realized by employing polyfunctional macromers or monomers. See, particularly, the abstract, columns 4-5, column 6, lines 52-62, the example in columns 9-12 and the claims. When used as wound dressing composition, the copolymer may be incorporated with

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therapeutical agents as served as sustained release device. See, particularly, column 8, line 48-63.

As to the employment of the particularly moiety defined in claims 47, note, acrylate and lactate are known to be useful in the macromer, therefore, employ the ester of the two compounds herein is obvious. Polymerization initiator is required in Zajaczkowski's composition. See, particularly, the examples.

Zajaczhowski does not teach expressly to employ a macromers having at least two polymerizable groups, or the particular, macromers.

However, Hubbell et al. teach a biocompatible, biodegradable, polymerizable and at least substantially water soluble macromers having a variety of uses in vivo. The macromer has molecular weight about 400 to 30,000, and has polyethylene glycol moiety and alpha hydroxyl acid moiety, such as lactic acid. The macromer has at least two polymerizable terminal acrylate moieties. The hydrogel obtained from the macromer is particularly useful for wound dressing, tissue adhesives, tissue support, and control release of therapeutical agents. The macromer may be polymerized by a photoinitiator. See column 9.

Therefore, it would have been prima facie obvious to a person of ordinary skill in the art, at the time the claimed the invention was made, to employ the macromers as disclosed by Hubbell et al. to make the crosslinked water-absorbent copolymers.

A person of ordinary skill in the art would have been motivated to employ the macromers as disclosed by Hubbell et al. to make the crosslinked water-absorbent copolymers because of the advantage disclosed by Hubble, e.g., biocompatible, biodegradable, polymerizable, and further the macromer has more than one polymerizable groups, meet the requirement for internal crosslinking as defined by Zajaczhowski, and provide a means of crosslinking. Further, the

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macromer has similar molecular weight and components to those employed by Zajaczhowski, and is particularly known to be useful in forming materials suitable for tissue adhesive wound dressing and controlled release.

3. Claims 38-53 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zajaczkowski (US 5,726,250) in view Jarrett et al. (WO 98/12243, IDS).

Zajaczhowski teaches a crosslinked water-absorbent copolymers useful for wound dressing and medical adhesive. The copolymer is made of macromers and monomers, wherein the macromer has a hydrophilic region, which may be polyethylene glycol, and acrylate terminal, with molecular weight about 300-50,000, and preferably 300 to 3000; the monomers may be hydrophilic, such as hydroxyethyl acrylate, vinyl pyrrolidone, diacetone acrylamide, or hydrophobic, such as butyl acrylate. The amount of macromer may up to 35 % by weight. The crosslinking may be realized by employing polyfunctional macromers or monomers. See, particularly, the abstract, columns 4-5, column 6, lines 52-62, the example in columns 9-12 and the claims. When used as wound dressing composition, the copolymer may be incorporated with therapeutical agents as served as sustained release device. See, particularly, column 8, line 48-63. Polymerization initiator is required in Zajaczkowski's composition. See, particularly, the examples.

Zajaczhowski does not teach expressly to employ a macromers having at least two polymerizable groups, or the particular, macromers.

However, Jarrett et al. teaches a macromer containing polyethylene glycol moiety and carbonate moiety (e.g., trimethylene carbonate), and/or lactate moiety, and with more than one terminal acrylate groups. The macromer is particularly useful for adhere or seal tissues together

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(wound dressing), or for controlled delivery of therapeutic agent. See, particularly, the abstract, pages 23-24, and the claims. The macromer is advantageous because it can be used to coat and or bond together any of a wide variety of surfaces, including bone or cartilage. See pages 30-31.

Therefore, it would have been *prima facie* obvious to a person of ordinary skill in the art, at the time the claimed invention was made, to employ the macromers as disclosed by Jarrett et al. to make the crosslinked water-absorbent copolymers.

A person of ordinary skill in the art would have been motivated to employ the macromers as disclosed by Jarrett et al. to make the crosslinked water-absorbent copolymers because of the known advantage of the macromer, such as it can be used to coat and or bond together any of a wide variety of surfaces, including bone or cartilage. Further, the macromer has more than one polymerizable groups, meet the requirement for internal crosslinking as defined by Zajaczhowski, providing a means for crosslinking. Further, the macromer has similar molecular weight and components to those employed by Zajaczhowski, and is particularly known to be useful in forming materials suitable for wound dressing and controlled release. As to the employment of the particular moiety defined in claims 47, note, acrylate and lactate are known to be useful in the macromer, therefore, employ the ester of the two compounds herein is obvious. As to the particular physical properties herein recited, note a composition, as suggested herein, comprising the macromer, e.g., 35KT (example in Jarret) and the monomer disclosed by Zajaczhowski would reasonably meet the limitation since the composition meet all the material limitations herein recited. Note a physical property of a composition cannot be separated from the composition. Further, one of ordinary skill in the art would have reasonable expected the

composition as suggested herein would be useful for bonding or repairing bone or cartilage since the macromer is particularly known for such purpose.

***Response to the Arguments***

Applicants' amendments and remarks submitted June 14, 2004 have been fully considered, but are not persuasive.

Applicants argue that the macromer employed by Zajaczhowski is different from the one disclosed by the secondary reference or employed herein. Particularly, applicants argue that the macromer employed by Zajaczhowski does not have a hydrophobic region and the two polymerizable moieties as claimed herein. First, the examiner noted that the rejections are based on the combination of all cited references. Considering the cited references as a whole, the claimed invention would have been obvious to one of ordinary skill in the art. Further, Zajaczhowski does not require the macromer to be composed of hydrophilic moiety only, but only be substantially water soluble. The macromers disclosed by the secondary references certainly meet such limitation. As to the two polymerizable moieties, note Zajaczhowski particularly requires the composition be crosslinked, and states that the crosslinking may be realized by a variety of means, including internal crosslinking. One of ordinary skill in the art would have been motivated to employ the macromer disclosed by the secondary references because, in addition to other known advantages, the macromer would also function as crosslinking agent. No additional crosslinking agents would required.

As to the physical properties herein claimed, i.e., modulus, note, a physical property of a composition cannot be separated from the composition. If the composition were old or otherwise

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obvious, a recitation of a particular physical property would not make the composition distinct from the old or otherwise obvious composition.

With respect to Hubbell's teaching, note Hubbell never limit the utility of the macromer to *soft* tissue. In fact Hubbell teach broadly that the macromer may be used for tissue adhesive, tissue support, etc. see, particularly, column 10-11.

4. In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). Particularly, the primary reference teaches a medical adhesive comprising a macromer, a monomer, and, if necessary, a crosslinking agent, which upon polymerization, forming a crosslinked polymer having hydrophilic region (the macromer) and hydrophobic region (the monomer). Secondary references teach the macromers herein employed and their advantages, in vivo utility, including as tissue adhesive. The macromer also have two polymerizable groups, and therefore, and are considered as a crosslinking agents. Considering the cited references as a whole, one of ordinary skill in the art would have been motivated to substitute the macromer in the primary reference with the macromers disclosed in the secondary references to take advantages of the macromers, which are biocompatible, biodegradable, having a variety of uses in vivo, and which can be used to coat and or bond together any of a wide variety of surfaces, including bone or cartilage. Further, the macromer may simultaneously function as crosslinking agents.



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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shengjun Wang whose telephone number is (571) 272-0632. The examiner can normally be reached on Monday to Friday from 7:00 am to 3:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan, can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

**SHENGJUN WANG**  
**PRIMARY EXAMINER**

Shengjun Wang  
Primary Examiner  
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